UNITED STATES DISTRICT COURT
FOR THE
EASTERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA, STATE OF CALIFORNIA; STATE OF DELAWARE; STATE OF FLORIDA; STATE OF HAWAII; STATE OF ILLINOIS; STATE OF LOUISIANA; COMMONWEALTH OF MASSACHUSETTS; STATE OF NEVADA; STATE OF NEW MEXICO; STATE OF NEW YORK; STATE OF TENNESSEE; STATE OF TEXAS; COMMONWEALTH OF VIRGINIA; and THE DISTRICT OF COLUMBIA; *EX REL.* JOSEPH PIACENTILE PLAINTIFF, *v.* NOVARTIS AG, NOVARTIS OPHTHALMICS, INC., and NOVARTIS PHARMACEUTICALS CORPORATION, DEFENDANTS.	**AMENDED COMPLAINT FILED UNDER SEAL PURSUANT TO 31 U.S.C. § 3730(b)(2)**

On behalf of the United States of America, and on behalf of the State of California, the State of Delaware, the State of Florida, the State of Hawaii, the State of Illinois, the State of Louisiana, the Commonwealth of Massachusetts, the State of Nevada, the State of New Mexico, the State of New York, the State of Tennessee, the State of Texas, the Commonwealth of Virginia, and the District of Columbia (collectively the "States"), Plaintiff and Relator Joseph

Piacentile, M.D. ("Dr. Piacentile" or "Relator") files this *qui tam* Amended Complaint against Defendants Novartis AG, Novartis Ophthalmics, Inc. and Novartis Pharmaceuticals Corporation (collectively "Novartis" or "Defendants") and alleges as follows:

I. INTRODUCTION.

A. Federal Law Claims.

1. This is an action to recover damages and civil penalties on behalf of the United States of America arising from the conduct of Novartis which: a) knowingly presented, or caused to be presented, to the Government a false or fraudulent claim for payment or approval; b) knowingly made, used, or caused to be made or used, false records or statements to get a false or fraudulent claim paid or approved by the Government; and/or c) knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the Government, all in violation of the False Claims Act, 31 U.S.C. §§ 3729 *et seq*. (the "False Claims Act" or "FCA").

2. The false or fraudulent claims, statements and/or records at issue involve payments for Novartis prescription drugs made by federal government-funded health insurance programs, such as the Federal Employees Health Benefits Program ("FEHBP"), the United States Military's health care plan for military personnel ("TRICARE") and the Civilian Health and Medical Program of the Veterans Administration ("CHAMPVA"), by the federal government-funded assistance program Medicare, and by the federal and state government-funded assistance program Medicaid.

B. State Law Claims.

3. This is also an action to recover double and treble damages and civil penalties on behalf of the named States arising from the conduct of Novartis which: a) made, used or

presented, or caused to be made, used or presented, certain false or fraudulent statements, records and/or claims for payment or approval to the States; and/or b) made, used or caused to be made or used false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the States, all in violation of each State's respective false claims act or similar statute. The false or fraudulent claims, statements and records at issue involve payments made by health insurance programs funded by these State governments, including Medicaid.

4. The statutes of the States under which Relator brings these related actions are the:

a. California False Claims Act, Cal. Govt. Code §§ 12650 *et seq.*;

b. Delaware False Claims and Reporting Act, Del Code Ann. tit. 6, §§ 1201 *et seq.*;

c. Florida False Claims Act, Fla. Stat. §§ 68.081 *et seq.*;

d. Hawaii False Claims Act, Haw. Rev. Stat. §§ 661-21 *et seq.*;

e. Illinois Whistleblower Reward and Protection Act, 740 Ill. Comp. Stat. §§ 175/1 *et seq.*;

f. Louisiana False Claims Act/Medical Assistance Programs Integrity Law, La. Rev. Stat. §§ 46:437.1 *et seq.*;

g. Massachusetts False Claims Law, Mass. Gen. Laws ch. 12 §§ 5A *et seq.*;

h. Nevada False Claims Act, Nev. Rev. Stat. §§ 357.010 *et seq.*;

i. New Mexico Medicaid False Claims Act, N.M. Stat. §§ 27-14-1 *et seq.*;

j. New York False Claims Act, N.Y. Fin. Law §§ 187 *et seq.*;

k. Tennessee Medicaid False Claims Act, Tenn. Code §§ 71-5-181 *et seq.*;

l. Texas Medicaid Fraud Prevention Law, Tex. Hum. Res. Code §§ 36.001 *et seq.*;

m. Virginia Fraud Against Taxpayers Act, Va. Code §§ 8.01-216.1 *et seq.*; and

n. District of Columbia False Claims Act, D.C. Code §§ 2-308.03 *et seq.*

II. SUMMARY OF THE ALLEGATIONS.

A. The Defendants' Unlawful Conduct.

5. From in or about 2000, and continuing through at least in or about 2006, Novartis routinely entered into arrangements with, and/or paid kickbacks to, physicians in order to illegally influence their diagnoses, prescription decisions and/or billing protocols. All of this misconduct was designed and intended to induce the physician to prescribe Novartis drugs rather than competing drugs, and thereby increase Novartis' prescription-drug market share and its profits.

6. The major misconduct alleged in this action centers around two drugs whose target patient populations were the elderly. Novartis engaged in a practice of preying upon those elderly patients through biased direct-to-patient presentations and screenings conducted by Novartis personnel in conjunction with physicians who Novartis promoted and financially assisted.

7. The first of these drugs is Visudyne – a physician-administered, intravenous drug, given in several doses over time, that reacts to laser light to treat "wet" macular degeneration (bleeding from blood vessels in the eye's retina that causes loss of vision or blindness). As to this drug, the kickbacks and arrangements included ophthalmologist participation with Novartis personnel in it's "Seeing-Eye-to-Eye" program conducted at residential elder-care facilities which, through direct-to-patient presentations and on-site 'diagnoses', steered patients to the participating physician that Novartis financed with credit lines up to $1 million to purchase and administer Visudyne.

Novartis also provided other valuable services at no cost, such as on-site billing "consultants" that ensured the physician maximized the potential reimbursements available from third-party payors, including the Government.

8. The second of these drugs is Miacalcin Nasal Spray – a patient-administered, long-term treatment for osteoporosis in post-menopausal women with low bone mass.. As to this drug, the kickbacks and arrangements included direct-to-patient bone-density screening programs conducted by Novartis personnel in the participating physician's office. The screenings identified osteoporosis patients with bone-density levels low enough to qualify for Medicare reimbursement of the drug.

9. Novartis also used kickbacks to reward and secure physician loyalty to prescribing Novartis drugs before moving top sales reps to launch the Visudyne program. The drugs implicated by these kickbacks included:

- GenTeal -- prescription eye drops to treat "dry eye";
- Rescula -- prescription eye drops to treat glaucoma;
- Voltaren Ophthalmic -- prescription eye drops to treat inflammation; and
- Lotrel -- an oral medication to treat high blood pressure

10. The kickbacks Novartis paid to prescribing physicians came in many forms, including cash payments, often disguised as "research grants" or "speaking fees," free consulting services, price discounts, untracked free samples of physician-administered drugs (such as Visudyne), forgiveness of drug-acquisition loan payments, and other inducements.

11. By paying illegal kickbacks and offering price discounts to physicians, in violation of the Anti-Kickback Act of 1986, 41 U.S.C. §§ 51 *et seq.* (the "Anti-Kickback Act"), the Medicare/Medicaid Anti-Kickback Statute, 42 U.S.C. §§ 1320a-7a & 7b(b) (the "Anti-

Kickback Statute") and the Stark Law, 42 U.S.C. § 1395nn (the "Stark Law"), Novartis caused and/or induced physicians who sought reimbursement for Novartis drugs from federal government-funded health insurance and assistance programs to file false, and/or fraudulent certifications, either express or implied, regarding compliance with the Anti-Kickback Act, the Anti-Kickback Statute, the Stark Law, and/or applicable state statutes.

12. The Government has deemed such misconduct to be material to its decision to pay healthcare claims, in part through its requirement that providers certify compliance with these laws as a condition of payment under, and participation in, Government healthcare programs. If the Government had been aware that drugs were prescribed as a result of such prohibited conduct, the Government would not have paid the claims submitted as a result of Novartis' wrongdoing.

13. Hence, by and through its conduct, Novartis knowingly, either directly or indirectly, caused presentment to the Government of false or fraudulent claims for payment or approval, and/or caused the making or using of false or fraudulent records or statements to get false or fraudulent claims paid or approved by the Government, all in violation of 31 U.S.C. §§ 3729(a)(1) and (2) and applicable state statutes.

14. Novartis's actions have illegally moved market share to specific Novartis drugs by inducing physicians to prescribe medications they would not otherwise have prescribed but for the receipt of kickbacks and price discounts.

15. In addition, the provision of untracked free samples and other things of value in connection with physician-administered drugs demonstrate that Novartis could not have properly taken those concessions into consideration when submitting statutorily mandated "Best Price" information to CMS. Thus, Novartis knowingly made false records or statements to the

Government when it failed to accurately report to the Government its "Best Price" information for those drugs. Novartis did so knowing that the Government would rely upon its reported "Best Price" to determine whether Novartis fully paid its statutory rebate obligations to the Government, and hence that by failing to report its "Best Price" the Government would have no means of determining that Novartis underpaid rebates to the Government. As a result, Novartis also knowingly failed to pay the full rebate due and owing to the respective states administering the Medicaid program, which concomitantly caused the federal government to pay more than it otherwise would have to cover its portion of the cost of the drug under the Medicaid program, in violation of law.

16. To avoid detection of false or fraudulent claims, and to avoid its obligations to report its "Best Price" and fully pay refunds to state Medicaid programs, Novartis falsely certified or caused others to falsely certify that the claims submitted or caused to be submitted were made in compliance with federal and state laws governing the integrity of claimant conduct, including the prohibitions against kickbacks and illegal remuneration to physicians, and against physician referrals for outpatient drugs manufactured by an entity with which the physician has a direct or indirect financial relationship.

17. As a result of its unlawful conduct, Novartis facilitated and caused false, fraudulent and improper billings that induced Medicare, Medicaid and other government-funded programs to pay hundreds of millions of dollars in unqualified and/or inflated reimbursements, some to undeserving physicians, and all at taxpayer expense. The Government would have refused to pay such claims if it had been aware that the claims were tainted by misconduct the Government deemed material to its decision to pay. Novartis, in turn, earned enormous profits.

III. JURISDICTION, VENUE AND SPECIAL REQUIREMENTS.

18. Pursuant to 28 U.S.C. § 1331, this District Court has original jurisdiction over the subject matter of this civil action since it arises under the laws of the United States, in particular the False Claims Act. In addition, the FCA specifically confers jurisdiction upon the United States District Court, 31 U.S.C. § 3732(b).

19. Pursuant to 28 U.S.C. § 1367, this District Court has supplemental jurisdiction over the subject matter of the claims brought pursuant to the false claims acts of the States on the ground that the claims are so related to the claims within this Court's original jurisdiction that they form part of the same case or controversy under Article III of the United States Constitution.

20. This court has personal jurisdiction over the Defendants pursuant to 31 U.S.C. § 3732(a) because the FCA authorizes nationwide service of process and the Defendants have sufficient minimum contacts with the United States of America.

21. Venue is proper in this District pursuant to 31 U.S.C. § 3732(a) because the acts complained of herein occurred in the State of New York within this judicial district.

22. In accordance with 31 U.S.C. § 3730(b)(2), the original Complaint and this Amended Complaint have been filed *in camera* and will remain under seal for a period of at least 60 days and shall not be served on the Defendants until the Court so orders.

23. Pursuant to 31 U.S.C. § 3730(b)(2), the Relator must provide the Government with a copy of the Complaint and/or a written disclosure of substantially all material evidence and material information in its possession contemporaneous with the filing of the Complaint. Relator has complied with this provision by serving copies of the initial Complaint on Rosalyn R. Mauskopf, then United States Attorney for the Eastern District of New York and John

Ashcroft, then Attorney General for the United States of America, and copies of this Amended Complaint on Benton Campbell, United States Attorney for the Eastern District of New York, and on Michael Mukasey, Attorney General for the United States of America.

IV. THE PARTIES.

24. Dr. Piacentile resides in the state of New Jersey and is a licensed, non-practicing physician engaged in the healthcare industry. Dr. Piacentile brings this action for violations of the False Claims Act on behalf of himself, the United States of America pursuant to 31 U.S.C. § 3730(b)(1), and the enumerated states pursuant to their respective false claims acts.

25. Dr. Piacentile has personal knowledge of the Defendants' practices as a result of an extensive undercover investigation he personally conducted in which he secured admissions from former sales representatives of Novartis regarding the allegations set forth herein.

26. Relator is not aware of any "public disclosure" in connection with the false claims alleged in this Complaint as defined in 31 U.S.C. § 3730(e)(4)(A). Even if any public disclosures are found to have occurred, this Court has jurisdiction because Relator is an "original source" under the FCA on the grounds that he has knowledge which is both direct and independent of any public disclosures to the extent they may exist. In particular, Relator's knowledge was acquired in the course of conducting an undercover investigation of Novartis, including private conversations with two former Novartis sales representatives. Relator voluntarily provided the federal government the information in his possession prior to the filing of this lawsuit.

27. Defendant Novartis AG, headquartered in Basel, Switzerland, is a public company incorporated under the laws of Switzerland. Novartis AG was created in 1996 as the result of the merger of the Swiss companies, Sandoz AG and CIBA-Geigy AG. According to

Novartis AG, its core businesses are in pharmaceuticals, consumer health, generics, eye-care, and animal health. From 2003 through 2007, Novartis AG's businesses achieved sales totaling approximately $150 billion and a net income of approximately $35.5 billion.

28. Defendant Novartis Pharmaceuticals Corporation is a foreign business corporation incorporated in the state of Delaware with its principal place of business located in East Hanover, New Jersey.

29. Defendant Novartis Ophthalmics, Inc. is a foreign business corporation incorporated in Delaware with its principal place of business located in East Hanover, New Jersey. Novartis Ophthalmics, Inc. is the eye health unit of Novartis Pharmaceuticals Corporation.

V. GOVERNING LAWS, REGULATIONS AND CODES OF CONDUCT.

A. The False Claims Act.

30. Originally enacted in 1863, the FCA was substantially amended in 1986 by the False Claims Amendments Act. The 1986 amendments enhanced the Government's ability to recover losses sustained as a result of fraud against the United States.

31. The False Claims Act, specifically 31 U.S.C. § 3729(a)(1), (2) & (7), imposes liability upon any person who: "knowingly presents, or causes to be presented [to the Government] a false or fraudulent claim for payment or approval;" or "knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved;" or "knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Government." Any person found to have violated these provisions is liable for a civil penalty of up to $11,000 for each such false or fraudulent claim, plus three times the amount of the

damages sustained by the Government.

32. In general, the False Claims Act imposes liability where the conduct is merely "in reckless disregard of the truth or falsity of the information" and further clarifies that "no proof of specific intent to defraud is required." 31 U.S.C. § 3729(b).

33. The False Claims Act also broadly defines a "claim" as one that "includes any request or demand, whether under a contract or otherwise, for money or property which is made to a contractor, grantee, or other recipient if the United States Government provides any portion of the money or property which is requested or demanded, or if the Government will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded." 31 U.S.C. § 3729(c).

34. The FCA empowers private persons having information regarding a false or fraudulent claim against the Government to bring an action on behalf of the Government and to share in any recovery. The complaint must be filed under seal without service on any Defendants. The complaint remains under seal while the Government conducts an investigation of the allegations in the complaint and determines whether to intervene in the action. 31 U.S.C. § 3730(b).

35. In this action, and under well-established precedent, the false or fraudulent nature of Defendants' conduct is informed or measured by their violation of, or failure to comply with certain statutes and regulations material to their drugs' qualification for reimbursement under Medicare and Medicaid.

B. FDA Regulation of Prescription Drugs.

1. FDA Approval of New Drugs.

36. Pursuant to the Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-97 (the "FD&C

Act"), new pharmaceutical drugs cannot be distributed in interstate commerce unless the sponsor of the drug demonstrates to the satisfaction of the U.S. Food & Drug Administration (the "FDA") that the drug is safe and effective for each of its intended uses. 21 U.S.C. § 331(d) (prohibiting distribution of any drug in violation of section 355); 21 U.S.C. § 355(a) & (d) (prohibiting distribution of any drug unless approved as safe and effective for the approved use).

37. The FDA only approves a drug for treatment of a specific condition or for a particular use for which the drug has been shown to be safe and effective, rather than granting a general approval. The specific approved treatment or use is referred to as the "indication" in the FDA-approved labeling and in scientific literature.

2. **Prohibition Against Manufacturer's Misbranding of Drugs.**

38. The FD&C Act further requires that all communications by a drug manufacturer about a drug be limited to the approved indication and cannot be misleading in any manner. In particular, 42 U.S.C. § 331(a), "Prohibited Acts," expressly prohibits "[t]he introduction or delivery for introduction into interstate commerce of any . . . drug . . . that is . . . misbranded." Pursuant to 21 U.S.C. § 352, "Misbranded drugs and devices," and its enabling regulations, a drug is misbranded when the manufacturer's labeling (which is defined to include not only the drug's physical packaging, but also all other written, audio or visual communications about a prescription drug), is "false, lacking in fair balance or otherwise misleading." Prescription-drug Advertisements, 21 C.F.R. § 202.1. For example, advertisements must contain a brief summary relating to a drug's side effects, contraindications and effectiveness.

39. The FD&C Act also deems the omission of information relevant to approved and known intended uses as a form of misbranding. Pursuant to the statute,

> [i]f an article is alleged to be misbranded because the labeling or advertising is misleading, then in determining whether the labeling or advertising is

> misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling or advertising fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling or advertising relates under the conditions of use prescribed in the labeling or advertising thereof or under such conditions of use as are customary or usual.

21 U.S.C. § 321(n).

C. Federal Government-Funded Health Assistance Programs.

1. Medicare.

a. Generally.

40. Medicare is a federal government-funded medical assistance program, primarily benefiting the elderly, that was created in 1965 when Congress enacted Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395 *et seq.* Medicare is administered by the federal Centers for Medicare and Medicaid Services ("CMS"), known prior to 2001 as the Health Care Financing Administration, which is a division of the U.S. Department of Health and Human Services ("HHS"). Medicare spending rose from $338 billion in 2005 to $401.3 billion in 2006 with the increase due largely to the January 1, 2006 implementation of Medicare Part D, which provides coverage for outpatient prescription drugs.

41. Prior to January 1, 2006, Medicare did not pay for over-the-counter drugs or most self-administered prescription drugs, although it did pay for certain drugs used by Medicare beneficiaries, including Visudyne.

b. "Reasonable and Necessary" Precondition to Payment.

42. Under Medicare, reimbursement is prohibited if the item or service is not "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." 42 U.S.C. § 1395y(a)(1)(A).

c. **The Stark Law's Prohibition Against Certain Financial Relationships.**

43. Under the Stark Law section of Medicare, if a physician has a direct or indirect financial relationship with an entity (*e.g.*, a drug manufacturer), then "the physician may not make a referral to the entity for the furnishing of designated health services for which payment otherwise may be made under this subchapter." 42 U.S.C. § 1395nn(a) and 42 C.F.R. § 411.353. The implementing regulations specifically define "designated health services" ("DHS") to include "[o]utpatient prescription drugs," which, in turn, are defined as "all drugs covered by Medicare Part B or Part D." 42 C.F.R. § 411.351 ("Definitions"). Hence, if a physician has a direct or indirect financial relationship with a drug manufacturer, the physician may not prescribe that manufacturer's drugs to patients covered by federally-funded healthcare programs.

44. The Stark Law incorporates many of the same concepts and terminology set forth in the Anti-Kickback Statute, such as prohibiting compensation to a physician that takes into account the "volume or value" of referrals to the entity.

45. The Stark Law also specifically incorporates portions of the Anti-Kickback Statute (*e.g.*, 42 U.S.C. § 1320a-7a concerning civil monetary penalties) and also imposes its own civil penalties of $15,000 for each false claim caused to be presented which is found to be the product of an improper financial arrangement. 42 U.S.C. § 1395nn(g)(3). In addition, the law heavily targets the entities (*e.g.*, drug manufacturers) dealing with physicians and imposes a $100,000 civil penalty upon the entity "for each such arrangement or scheme." 42 U.S.C. § 1395nn(g)(4).

46. The Government has deemed such misconduct to be material to its decision to pay healthcare claims, in part through its requirement that providers certify compliance with this law as a condition of payment under, and participation in, Government healthcare programs. If the

Government had been aware that drugs were prescribed as a result of such prohibited conduct, the Government would not have paid the claims submitted as a result of Novartis' wrongdoing.

2. Medicaid.

a. Generally.

47. The Medicaid program was also created in 1965 when Congress enacted Title XIX of the Social Security Act to expand the nation's medical assistance program to cover the medically needy aged, the blind, the disabled, and needy families with dependent children. 42 U.S.C. §§ 1396-1396v. The Medicaid program is funded by both federal and state monies, (collectively referred to as "Medicaid Funds"), with the federal contribution computed separately for each state. 42 U.S.C. §§ 1396b; 1396d(b). At the federal level, Medicaid is administered by CMS. Medicaid is used by 49 states, each of which has a state Medicaid agency to administer the program. Medicaid spending dropped slightly from $313.5 billion in 2005 to $310 billion in 2006 as some dual eligible persons moved their outpatient drug coverage to Medicare Part D.

48. Each state is permitted, within certain parameters, to design its own medical assistance plan, subject to approval by the HHS. Among other forms of medical assistance, the states are permitted to provide medical assistance from the Medicaid Funds to eligible persons for inpatient and outpatient prescription drugs. 42 U.S.C. § 1396a(10)(A); 1396d(a)(12).

b. "Medically Accepted Indication" Precondition for Reimbursement of Prescription Drugs.

49. The Medicaid program reimburses only for "covered outpatient drugs" for which a rebate is paid by the drug's manufacturer. 42 U.S.C. § 1396b(i)(10). The term "covered outpatient drug" requires use for a "medically accepted indication." 42 U.S.C § 1396r-8(k)(3). A "medically accepted indication" includes only those indications approved by the FDA, and those "off-label" uses that are "supported by one or more citations included or approved for inclusion

in any of the compendia" listed in the statute. 42 U.S.C. § 1396r-8(k)(6); *see also* 42 U.S.C. § 1396r-8(g)(1)(B)(i) (identifying the compendia to be consulted). Certain drugs that are not otherwise covered may be covered where the drugs have been determined to be "essential to the health of beneficiaries." 42 U.S.C. § 1396r-8(a)(3). This narrow exception has no application in this case.

50. Each state Medicaid program has the power to exclude any drug from coverage if the prescription is not issued for a "medically accepted indication." 42 U.S.C. § 1396r-8(d)(1)(B).

c. **Medicaid "Best Price" Reporting and Rebate Requirements.**

51. Each state pays a portion of the Medicaid cost for goods and services provided to that state's Medicaid beneficiaries. Each state's portion varies depending upon various factors, but generally ranges from 40-60%, with the federal government paying the remaining portion.

52. In 1990, Congress enacted the Medicaid Rebate Program, 4 U.S.C. § 1396r-8, as part of the Omnibus Budget Reconciliation Act of 1990. The Medicaid Rebate Program (also known as the Medicaid Rebate Act and the Medicaid Rebate Statute) is a cost-savings measure Congress passed in response to increasing Medicaid expenditures for prescription drugs, requires drug companies to pay rebates to states on their Medicaid purchases.

53. Pursuant to 42 U.S.C. § 1396r-8(a)(1), drug manufacturers who want their drugs covered by Medicaid and Medicare must enter into a Rebate Agreement with the Secretary of HHS in order for federal matching funds to be made available under these programs for that manufacturer's covered outpatient drugs. Each participating manufacturer must execute the agreement, indicating acceptance and compliance with all provisions therein, including that the Rebate Agreement shall be construed in accordance with federal common law and that

ambiguities shall be interpreted in the manner which effectuates the statutory scheme.

54. The Rebate Agreement provides that the Secretary enters the agreement on behalf of HHS and all states and the District of Columbia (except to the extent they have in force an Individual State Agreement). Upon entering a Rebate Agreement with the Secretary, the manufacturer must pay a quarterly rebate directly to each participating state based on all of the manufacturer's drugs purchased by that state pursuant to its Medicaid plan during that quarter.

55. Pursuant to 42 U.S.C. § 1396r-8(c)(1),(2), for single source or innovator multiple source drugs, the basic rebate due on each unit paid for under the state plan is calculated as the greater of either (a) a flat 15.1% off of the average manufacturers' price ("AMP") or (b) the difference between the AMP and the lowest price available during the previous quarter rebate period, from the manufacturer to *any* wholesaler, retailer, provider, health maintenance organization, non-profit entity or non-excluded government entity (the "Best Price").

56. The Best Price must take into account "cash discounts, free goods that are contingent on any purchase requirement, volume discounts and rebates (other than rebates under this section)." 42 U.S.C. § 1396r-8(c)(1)(C)(ii). The Best Price also is determined without regard to special packaging, labeling, or identifiers on the dosage form or product or package, such as private labeling arrangements.

57. The Best Price also excludes sales at a nominal price made to defined non-profit, charitable entities and for researchers using the drugs for experimental or non-standard purposes, since such discounts are not intended for marketing purposes. 42 U.S.C. § 1396r(c)(1)(C)(ii)(III) & (D). The Rebate Agreement defines nominal price as any price less than 10% of the AMP in the same quarter for which the AMP is computed.

58. Drug manufacturers are required under the Medicaid Rebate Statute and the

Rebate Agreement to calculate and report their AMPs and Best Prices to the Secretary of HHS on a quarterly basis. 42 U.S.C. § 1396r-8(3)(A)(i); Rebate Agreement at § II(e). States are required to report their total Medicaid drug utilization to each manufacturer and the Secretary sixty days after the end of the rebate quarter. 42 U.S.C. § 13964-8(b)(2)(A). Using the manufacturer pricing data, CMS computes the unit rebate amount ("URA") to which the Medicaid utilization information may be applied by states when invoicing the Manufacturer for the rebate payment due. Using the Medicaid drug utilization data, manufacturers calculate and pay the states the rebates they believe are due and owing to each state.

59. The federal government has great financial interest in the Best Price Rebate program, since the statute provides that amounts received by the states from the manufacturers "shall be considered to be a reduction in the amount expended under the state plan in the quarter for medical assistance for purposes of section 1396b(a)(1) of this title." 42 U.S.C. § 1396R-8(B)(1)(b). Hence, the entire system is based upon the manufacturer's honesty in conveying to CMS the correct Best Price and AMP information. Any overstatement of the Best Price, intentional or unintentional, will cause an underpayment in rebate amounts to each state. In turn, the underpayments to each state result in the federal government's cost-sharing payment to each state to be greater than it otherwise would have been.

60. In or about May 2003, as a result of pervasive Best Price fraud, the HHS Office of Inspector General ("OIG") promulgated compliance materials which observed that manufacturers have "a strong financial incentive to hide *de facto* concessions" (in particular, kickbacks and price discounts) that could affect Best Price calculations and trigger increased Medicaid rebates.

61. The OIG also instructed manufacturers to report Best Prices which "accurately

take into account price reductions, cash discounts, free goods contingent on a purchase agreement, rebates, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits offered to some or all purchasers." In sum, according to the OIG "pharmaceutical manufacturers are responsible for ensuring the integrity of data they generate that is used for government reimbursement purposes."

62. In this action, Novartis knowingly made false records or statements to the Government when it failed to accurately report to the Government its "Best Price" information for Novartis pharmaceutical products. Novartis did so knowing that the Government would rely upon its reported "Best Price" to determine whether Novartis fully paid its statutory rebate obligations to the Government, and hence that by failing to report its "Best Price" the Government would have no means of determining that Novartis underpaid rebates to the Government. As a result, Novartis also knowingly failed to pay the full rebate due and owing to the respective states administering the Medicaid program, which concomitantly caused the federal government to pay more than it otherwise would have to cover its portion of the cost of the drug under the Medicaid program, in violation of law.

3. General Provisions Applicable to Both Medicare and Medicaid.

a. Prohibitions Against Claims for Services that Are Not Medically Necessary or Are Otherwise False or Fraudulent.

63. Federal law prohibits a person from knowingly presenting or causing to be presented to Medicare or Medicaid a claim for a medical or other item or service that the person knows or should know was "not provided as claimed," a claim for such items or services that is "false or fraudulent," or a claim that is "for a pattern of medical or other items or services that [the] person knows or should know are not medically necessary." 42 U.S.C. §§ 1320a-7a(a)(1)(A), (B) & (E). Violation of this section is subject to a civil monetary penalty of $10,000

for each item or service, plus damages measured as three times the amount of each claim submitted, and exclusion from further participation in the programs.

b. <u>The Anti-Kickback Statute Ensures Integrity of Underlying Conduct</u>.

64. The Anti-Kickback Statute prohibits kickbacks by providing a civil monetary penalty of $50,000 for each act by an individual or entity that violates 42 U.S.C. § 1320a-7a(a)(7), which defines "[i]mproperly filed claims" as "[a]ny person (including an organization, agency, or other entity . . . that commits an act described in paragraph (1) or (2) of section 1320a-7b(b) of this title." The statute defines "illegal remuneration" (*i.e.*, kickbacks) as:

> (1) whoever knowingly and willfully *solicits or receives* any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind –
>
> * * *
>
> (B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,
>
> * * *
>
> (2) whoever knowingly and willfully *offers or pays* any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person –
>
> * * *
>
> (B) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,

42 U.S.C. § 1320a-7b(b) (emphasis added). The offense is also a felony punishable by fines of up to $25,000 and imprisonment for up to five years. 42 U.S.C. § 1320a-7b(b).

65. In accordance with the Anti-Kickback Statute, Medicare and Medicaid regulations directly prohibit any provider from receiving remuneration paid with the intent to induce referrals that take into account the "volume or value" of any referrals or business generated. *See*

42 C.F.R. § 1001.952(f). Such remuneration amounts to a kickback and can increase the expenditures paid by Government-funded health benefit programs by leading to overutilization of prescription drugs and inducing medically unnecessary and excessive reimbursements. Kickbacks also effectively reduce patients' healthcare choices, because unscrupulous (or unknowing) physicians steer their patients to various drug products based on the physician's own financial interests rather than the patients' medical needs.

66. The Anti-Kickback Statute contains statutory exceptions and regulatory "safe harbors" excluding certain types of conduct from liability. *See* 42 U.S.C. § 1320a-7b(b)(3) and 42 C.F.R. § 1001.952. None of these statutory exceptions or regulatory safe harbors applies to Defendants' conduct in this matter.

67. The Medicare and Medicaid Patient and Program Protection Act of 1987 authorizes the exclusion of an individual or entity from participation in the Medicare and Medicaid programs if it is determined that the party has violated the Anti-Kickback Statute. In addition, the Balanced Budget Act of 1997 amended that Act to impose administrative civil monetary penalties for Anti-Kickback Statute violations: $50,000 for each act and an assessment of not more than three times the amount of remuneration offered, paid, solicited or received, without regard to whether a portion of such remuneration was offered, paid, solicited or received for a lawful purpose. *See* 42 U.S.C. § 1320a-7a(a)(7).

68. The Government has deemed such misconduct to be material to its decision to pay healthcare claims, in part through its requirement that providers certify compliance with this law as a condition of payment under, and participation in, Government healthcare programs. If the Government had been aware that drugs were prescribed as a result of such prohibited conduct, the Government would not have paid the claims submitted as a result of Novartis' wrongdoing.

D. Direct Federal Health Insurance Plans and Drug Pricing Contracts.

1. Direct Federal Health Insurance Plans.

a. TRICARE/CHAMPVA.

69. TRICARE, administered by the Department of Defense ("DoD"), is the United States military's health care system, designed to maintain the health of active duty service personnel, provide health care during military operations, and offer health care to non-active duty beneficiaries, including dependents of active duty personnel and military retirees and their dependents. In 2006, the military spent approximately $6.2 billion on pharmacy benefits. TRICARE operates through various military-operated hospitals and clinics worldwide and is supplemented through contracts with civilian health care providers. TRICARE is a triple-option benefit program designed to give beneficiaries a choice between health maintenance organizations, preferred provider organizations and fee-for-service benefits. Five managed care support contractors create networks of civilian health care providers. Military prescription drug benefits are provided through three programs: military treatment facility outpatient pharmacies, TRICARE contractor retail pharmacies and a national contractor's mail-order service.

70. Similarly, CHAMPVA, administered by the Department of Veterans Affairs (the "VA"), provides healthcare coverage to qualified families of deceased or 100% disabled veterans.

b. Federal Employees Health Benefits Plan ("FEHBP").

71. The FEHBP provides health insurance coverage for nearly 8.7 million federal employees, retirees and their dependents. The FEHBP is a collection of individual health care plans, including the Blue Cross and Blue Shield Association, Government Employees Hospital Association, and Rural Carrier Benefit Plan. FEHBP plans are managed by the Office of

Personnel Management and collectively pay more than $2 billion annually in prescription drug benefits.

2. <u>Federal Agencies Directly Purchasing Drugs</u>.

a. <u>The Department of Veterans Affairs</u>.

72. The VA maintains a system of medical facilities that contracts for the purchase of prescription drugs, which are then administered and/or dispensed to beneficiaries directly by VA facilities, or through mail order or retail pharmacies.

b. <u>The Department of Defense</u>.

73. The DoD negotiates independent contracts with drug manufacturers, including Novartis, for the purchase of prescription drugs, which are provided to approximately 8 million active and retired military personnel and their families via TRICARE managed care contractor retail pharmacies, mail order pharmacies, military treatment facility outpatient pharmacies, and DoD-operated medical care facilities.

3. <u>The Anti-Kickback Act</u>.

74. Parties who contract or subcontract with the federal government are subject to the provisions of the Anti-Kickback Act. That law renders it impermissible for any person "to provide, attempt to provide, or offer to provide any kickback," and defines 'kickback' to mean "any money, fee, commission, credit, gift, gratuity, *thing of value*, or compensation of any kind which is provided, directly or indirectly, to any prime contractor, prime contractor employee, subcontractor, or subcontractor employee *for the purpose of improperly obtaining or rewarding favorable treatment* in connection with a prime contract or in connection with a subcontract relating to a prime contract." 41 U.S.C. §§ 52 -53 (emphasis added). This broad language reflects Congress's intent to prohibit even *attempts* to offer or provide a kickback, and to include

a wide array of benefits and activities within its scope.

75. The Government has deemed such misconduct to be material to its decision to pay healthcare claims, in part through its requirement that providers certify compliance with this law as a condition of payment under, and participation in, Government healthcare programs. If the Government had been aware that drugs were prescribed as a result of such prohibited conduct, the Government would not have paid the claims submitted as a result of Novartis' wrongdoing.

E. Other Standards Bearing on the Integrity of Conduct.

1. PhRMA Code on Interactions.

76. In or about July 2002, the Executive Committee of the Pharmaceutical Research and Manufacturers of America ("PhRMA"), of which Defendant Novartis was a member, adopted a detailed (but voluntary) marketing code (the "PhRMA Code") intended to govern the industry's relationships with physicians and other healthcare professionals. According to a PhRMA press release, the Code "explicitly spells out that all interactions should be focused on informing healthcare professionals about products, providing scientific and educational information, and supporting medical research and education" in a manner that "benefit[s] patients and enhance[s] the practice of medicine."

77. In relevant part, the PhRMA Code prohibited drug companies from paying "token consulting or advisory arrangements" as a justification for defraying travel, lodging, and other out-of-pocket expenses; prohibited "grants, scholarships, subsidies, support, consulting contracts, or educational or practice-related items" in exchange for "prescribing products or for a commitment to continue prescribing products;" prohibited paying for all but modest meals in connection with a sales rep visit or a medical lecture; and prohibited providing entertainment or other recreational activities.

2. OIG Guidance.

78. In or about April 2003, the OIG issued its Compliance Program Guidance for Pharmaceutical Manufacturers ("OIG Guidance"). The OIG Guidance suggested which interactions between drug manufacturers and physicians have been appropriate and which interactions were potentially subject to civil and/or criminal liability under the False Claims Act, the Anti-Kickback Statute, and the Stark Law. Although the OIG Guidance acknowledged that the PhRMA Code provided a "good starting point" for compliance, it did not endorse the Code as a "safe harbor" that would guarantee protection from civil or criminal liability.

79. The OIG Guidance declared that free or discounted equipment or services provided to the physician, such as computers, faxes or business management consulting services to physicians, were "suspect" under the Anti-Kickback Statute, as were educational grants and payments to physicians for supposed "consulting services."

80. Further, the OIG Guidance provided that research contracts that originated through the sales and marketing functions – or that were offered to doctors in connection with sales contacts – wer e particularly "suspect" under the Anti-Kickback Statute. For example, research that was initiated or directed by sales or marketing agents that was not transmitted to the manufacturer's science division was considered of dubious legality.

3. American Medical Association Ethics Policy.

81. In or about December 1990, responding to drug companies' providing "increasingly lavish" gifts and payments to doctors in connection with seminars, conferences, and sales rep visits, the American Medical Association ("AMA") adopted an Ethical Opinion regarding "Gifts to Physicians from Industry." The policy stated that "[t]o avoid the acceptance of inappropriate gifts, physicians should observe the following guidelines:

> (1) Any gifts accepted by physicians individually should primarily entail a benefit to patients and should not be of substantial value. . . Cash payments should not be accepted.
>
> (2) Individual gifts of minimal value are permissible as long as the gifts are related to the physician's work (*e.g.*, pens and notepads).
>
> * * *
>
> (7) No gifts should be accepted if there are strings attached. For example, physicians should not accept gifts if they are given in relation to the physician's prescribing practices. In addition, when companies underwrite medical conferences or lectures other than their own, responsibility for and control over the selection of content, faculty, educational methods, and materials should belong to the organizers of the conferences or lectures.

PhRMA accepted and adopted these guidelines.

82. The AMA's Ethical Opinion regarding "Prescribing and Dispensing Drugs and Devices" required doctors to "prescribe drugs . . . solely upon medical considerations and patient need and reasonable expectation, of the effectiveness of the drug . . . or the particular patient." The Opinion expressly prohibited physicians from accepting "any kind of payment or compensation from a drug company . . . for prescribing its products."

4. American College of Physicians Ethics Manual.

83. Similarly, the American College of Physicians' Ethics Manual ("Ethics Manual") recognized "drug industry gifts" as having potentially negative influence on clinical judgment and noted that it was "unethical for a physician to receive a commission or a kickback from anyone, including a company that manufactures or sells . . . medications that are used in the care of the physician's patients."

VI. SPECIFIC ALLEGATIONS.

A. Visudyne.

84. In April 2000 the FDA approved Novartis's Visudyne therapy as the first

treatment indicated for wet macular degeneration. The therapy included several physician-administered injections of Visudyne, a drug that was light-activated via targeted use of a non-thermal ("cold") laser. As a physician-administered drug, Visudyne was reimbursable under Medicare as well as Medicaid.

85. Novartis sought to capitalize on Visudyne's first-to-market competitive advantage by moving its best sales people onto the Visudyne sales team to quickly identify potential prescribing ophthalmologists and then bankroll the Visudyne portion of their practice. Novartis' objective was to establish and secure a substantial share of the wet macular degeneration treatment market before any competing drugs were approved.

1. **Visudyne "Seeing Eye-to-Eye" Physician Speakers Program.**

86. Beginning in or about 2000, Edward Davila, a Novartis Ophthalmics, Inc. sales representative between 1998 and 2002, recruited and trained physicians for the Visudyne "Seeing-Eye-to-Eye" Physician Speakers Program. Under the program, Novartis partnered with selected ophthalmologists and provided them with a line of credit of up to $1 million to finance an adequate stock of the $600 per dose, physician-administered drug Visudyne. Novartis personnel then set-up and facilitated direct-to-patient presentations at residential elder-care facilities and similar venues. The presentations steered patients away from their existing ophthalmologists and toward participating physicians through the use of hard-sell tactics and strategies.

87. The program included biased literature prepared by Novartis, a joint presentation by Novartis and the participating ophthalmologist, and on-site screenings by Novartis with immediate "diagnoses" by the physician -- notwithstanding the unavailability of the patient's full medical history. The entire program was designed to make the participating ophthalmologist

appear very knowledgeable and capable. In fact, it was designed to hook these vulnerable patients into believing that because the participating ophthalmologist was effectively endorsed by the manufacturer of this "breakthrough" drug, the participating ophthalmologist would provide care superior to what they would receive from their existing provider. In reality, however, the program subverted and undermined the physician's independent medical judgment.

88. The "Seeing-Eye-to-Eye" program was initiated in 2000 as an effort to capitalize on Visudyne's status as the first therapy approved for the treatment of wet macular degeneration. In August 2001, Visudyne also received FDA-approval for the treatment of pathological myopia (a form of nearsightedness) and presumed ocular histoplasmosis (a fungal infection of the eye), thus further extending the drug's share in the market.

89. Novartis described the "Seeing-Eye-to-Eye" program as:

> a traveling 30-minute talk show that visits senior centers and active adult communities with the goal of educating audiences about AMD [Age-Related Macular Degeneration] and Visudyne therapy. It also provides free AMD eye screenings. The show involves a local physician who discusses the AMD threat and the importance of regular eye exams.

90. Novartis also described the "Seeing-Eye-to-Eye" program and the benefits to each party as follows:

> a grassroots outreach program sponsored by Novartis Ophthalmics [to] educate[] audiences about AMD and Visudyne Therapy...[which] will generate awareness for AMD and regular eye exams, which can lead to more patients visiting the local doctor(s), which will lead to more Visudyne sales...[and] will raise community awareness for the doctor and identify their practice as one that manages AMD patients.

91. The typical "Seeing-Eye-to-Eye" scenario was as follows:

a. Novartis sales reps would typically target ophthalmologists wishing to build large practices and attempt to establish sales relationships.

b. The salesperson would advise the ophthalmologist that participation in the "Seeing-Eye-to-Eye" program involved the doctor giving a short talk to senior citizens followed by macular degeneration screenings provided by Novartis.

c. The salesperson represented that each presentation would likely produce a significant number of new patients for the ophthalmologist, at least two of who would be diagnosed with wet macular degeneration and thus qualify for treatment with Visudyne therapy.

d. Novartis sales representatives also actively marketed to ophthalmologists the highly profitable "spread" between the $600-per-dose price the physician paid for Visudyne, and the $1,200-per-dose reimbursement the physician would later receive from third-party payors, including government programs. Since the average patient would receive several injections over the course of a Visudyne treatment program, each wet macular degeneration patient was worth approximately $4,000 to the ophthalmologist -- and was worth $4,000 to Novartis.

92. The salesperson also explained that Novartis would pay all program costs and also provide a line of credit to finance an adequate stock of the drug. In exchange, the ophthalmologist would agree to treat his new patients using Visudyne and other Novartis drugs. In other words, the physician used the power of his prescription pad to pay Novartis for the valuable benefits it provided.

93. Mr. Davila conducted approximately 250 "Seeing-Eye-to-Eye" programs with local physicians per year. At least 40 other Novartis representatives were also conducting, in any given year, approximately 250 "Seeing-Eye-to-Eye" programs. In total, Novartis annually held

about 10,000 "Seeing-Eye-to-Eye" programs, which helped propel Visudyne's U.S. sales to over $100 million per year in 2001, and total U.S. sales of nearly $1 billion between 2000 and 2007.

94. Novartis only allowed physicians to participate in this program if they were willing to diagnose patients immediately at the senior centers where the presentations were given. Through this policy and practice, Novartis thus controlled and compromised the quality of the participating physicians' services and, in conjunction with Novartis's direct financing of the physicians' purchase of Novartis ophthalmic drugs, subjugated the physicians' professional judgments to Novartis's revenue objectives.

95. In addition to controlling these physicians, Novartis improperly steered patients by designing the presentation and accompanying literature so as to exclude any mention of potential side effects and otherwise failed to provide a fair and balanced presentation that included all facts material to the physicians' and patients' decision to commence and continue Visudyne therapy. These failures by Novartis constitute "misbranding" of a prescription drug by its manufacturer in violation of applicable law, including but not limited to 42 U.S.C. § 331(a), 21 U.S.C. § 352(f)&(n), and 21 U.S.C. § 321(n). Furthermore, Novartis's policy and practice unfairly targeted vulnerable senior citizens with tactics designed to compel decisions that would not be fully informed.

2. Free Billing Consulting Services Provided by Novartis Constituted Direct Involvement in the Preparation and Presentment of False or Fraudulent Claims.

96. Further, as part of the Seeing Eye-to-Eye program, Novartis provided free practice management consulting services to participating physicians. The objective of these services was to help the participating ophthalmologist fully capitalize on the "spread" between Visudyne's per-dose cost of about $600 and the third-party reimbursement of about $1,200.

97. In its simplest form, Novartis's services included providing the participating ophthalmologist with pre-written letters of "medical necessity," which were available online. The physician used those letters to bill third-party payors, including Medicare and Medicaid, resulting in the physician receiving full reimbursement of approximately $1,200 per treatment.

98. Novartis also provided participating ophthalmologists with far more sophisticated and comprehensive free practice management consulting services. In particular, Novartis paid Rick Gable of Dynamic Health Connections, Inc., a recognized leader in practice management consulting, to visit prescribing doctors' offices and remain on site for many days, providing consulting services worth thousands of dollars. Gable's services focused on billing procedures and were aimed at maximizing the number of claims for Visudyne that would be reimbursed by third party payors, including Medicare and Medicaid.

99. To the extent Novartis, by and through its paid consultants, trained, counseled, advised or assisted in the preparation of false or fraudulent claims, Novartis knowingly presented or caused to be presented to the Government a false or fraudulent claim for payment or approval.

100. To the extent Novartis, by and through its paid consultants, trained, counseled, advised or assisted in the preparation of false or fraudulent claims, Novartis knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government. Moreover, Novartis did so knowing that claims would be submitted to the Government which would effectively be relying upon those records or statements to determine whether to pay or approve the claims.

3. Novartis Provided Free Samples and Payment Forgiveness on Lines of Credit.

101. Mr. Davila and other Novartis sales representatives routinely gave physicians free sample vials of Visudyne in order to further reduce the physicians' total acquisition cost of the

drug and increase the physicians' overall profit after reimbursement from third party payors, including the federal and state Governments. These free samples further induced those physicians to prescribe Visudyne and other Novartis drugs.

102. To ensure that the ophthalmologist could maintain a stock of over 100 doses of Visudyne, at a cost of $600 per dose, Novartis provided participating ophthalmologists with lines of credit of up to $1 million. However, when certain physicians fell behind in their payments on the line of credit, Novartis sometimes "forgave" the back payments, effectively reducing the physician's net cost of the drug.

4. All of The Alleged Visudyne Marketing Misconduct Also Constituted Kickbacks and Illegal Referrals.

103. Novartis' provision of free services to set-up and facilitate the "Seeing Eye-to-Eye" Program, free billing consulting services, free untracked drug samples and forgiveness of drug-acquisition loan payments, separately and together were, in each instance, the provision of something of value to the physician, either directly or indirectly, as an inducement or reward for prescribing Novartis drugs. Such conduct constituted kickbacks in violation of the Anti-Kickback Act and/or the Anti-Kickback Statute, and the participation illegal referrals in violation of the Stark Law, as well as violations of similarly applicable state laws. At its core, such misconduct subverted and undermined the physician's independent medical judgment.

5. All of The Alleged Visudyne Marketing Misconduct Also Reduced the Price of Visudyne, But the Value Was Excluded From Novartis's "Best Price" Reporting and Rebate Payment Calculations.

104. In addition, Novartis' provision of free services to set-up and facilitate the "Seeing Eye-to-Eye" Program, free billing consulting services, free untracked drug samples and forgiveness of drug-acquisition loan payments, separately and together, effectively lowered the physician's net acquisition price of Visudyne. Novartis knowingly made false records or

statements to the Government when it failed to take the value of these items into account when it reported to the Government its "Best Price" information for Visudyne. Novartis did so knowing that the Government would rely upon its reported "Best Price" to determine whether Novartis fully paid its statutory rebate obligations to the Government, and hence that by failing to report its "Best Price" the Government would have no means of determining that Novartis underpaid rebates to the Government. As a result, Novartis also knowingly failed to pay the full rebate due and owing to the respective states administering the Medicaid program, which concomitantly caused the federal government to pay more than it otherwise would have to cover its portion of the cost of the drug under the Medicaid program, in violation of law.

B. Novartis Paid Cash, Speaker's Fees and Provided Other Valuable Benefits to Physicians to Secure Their Prescribing Loyalty for GenTeal, Rescula, Voltaren Ophthalmic and Lotrel.

1. Novartis Paid Cash and Other Things of Value to Prescribing Physicians.

105. As a preliminary step to marketing Visudyne, Novartis used cash and other things of value to reward and secure the existing accounts of top sales representatives it was transferring to the Visudyne effort. Novartis understood that physician loyalty to prescribing its drugs was, in large part, the result of its sales representatives' having established and maintained a positive relationship and rapport with physicians. Thus, when Novartis decided to move its best sales representatives onto the Visudyne sales team, it knew existing physician relationships developed by those sales representatives could be compromised.

106. In order to secure the loyalty of their existing clients, the transferring sales representatives were allocated substantial budgets with which to make cash payments and provide other valuable benefits to their physician clients who prescribed high volumes of Novartis drugs.

107. For example, Mr. Davila had a sales relationship with Dr. Gregory K. Harmon, the Chairman and CEO of the Glaucoma Foundation and Director of Glaucoma Services at New York Presbyterian Hospital. Dr. Harmon examined over 400 patients per week and frequently prescribed Novartis drugs including the prescription drugs Voltaren Ophthalmic and Rescula, and the over-the-counter drug GenTeal. In about 2000, Dr. Harmon expected and received cash payments from Novartis, disguised in the form of a grant, in exchange for prescribing Novartis medications.

108. As another example, Mr. Davila had a sales relationship with the two physicians who ran the New York Eye and Ear Clinic, a world-renowned institution that retained, trained, and/or influenced a large number of ophthalmologists. As a reward for their loyalty to Novartis drugs and to secure the relationship, Novartis paid the New York Eye and Ear Clinic a $100,000 grant in about 2000.

2. <u>All of the Alleged Misconduct Constituted Kickbacks and Illegal Referrals</u>.

109. Novartis's payment of money or providing things of value, separately and together were, in each instance, the provision of something of value to the physician, either directly or indirectly, as an inducement or reward for prescribing Novartis drugs. Such conduct constituted kickbacks in violation of the Anti-Kickback Act and/or the Anti-Kickback Statute, and the participation in illegal referrals in violation of the Stark Law, as well as violations of similarly applicable state laws. At its core, such misconduct subverted and undermined the physician's independent medical judgment.

C. <u>Miacalcin Nasal Spray</u>.

110. Mr. Robert Van Glahn worked as a Novartis sales representative between January 2000 and September 2001. Mr. Van Glahn primarily marketed Miacalcin Nasal Spray (a

synthetic hormone replacement indicated for the treatment of post-menopausal osteoporosis) and Lotrel (an angiotensin converting enzyme (ACE) inhibitor, indicated for the treatment of hypertension) to prescribing physicians.

1. **Bone Density Screening at No Cost to Physicians.**

111. Mr. Van Glahn was involved in Novartis's national marketing strategy for Miacalcin Nasal Spray. Although not as effective as oral medications, Miacalcin Nasal Spray had fewer side effects and was prescribed for daily use on a long-term basis. Thus, each new patient generated long-term sales revenue.

112. Novartis and its sales representatives knew that Medicare would pay for the drug as a treatment for osteoporosis if the patient's bone density were below a certain value, and also that Medicare would pay for certain bone density screenings for patients over a certain age. To capitalize on these government benefits, Novartis purchased numerous bone density screening machines and circulated them among its sales representatives, who were directed to provide bone density screenings at no cost to the physician or the patient.

113. At the direction of his superiors, Mr. Van Glahn conducted free bone density screenings using a testing machine provided by Novartis. Mr. Van Glahn would advise a participating physician to arrange for patients to be present on a certain day to undergo testing. Mr. Van Glahn then used Novartis funds to set up the program and provide free lunch to everyone involved. The primary purpose of the screening was to determine whether or not the physician's patients were good candidates to begin using Miacalcin Nasal Spray. Mr. Van Glahn, and many other Novartis salespersons, acted not only as sales personnel, but also as technical screening personnel who effectively made the diagnosis, knowing the threshold value required for Medicare coverage of the drug. Thus, sales representatives had improper access to

patient data and charts, and would use that information to pressure the physician to write a prescription for Miacalcin Nasal Spray, including by directly requesting that the physician do so based on the patient's information and screening results.

114. Novartis operated the same scheme in every one of its regional sales areas throughout the U.S.

2. **Speaking Fees Paid to Physicians Prescribing High Volumes of Miacalcin Nasal Spray.**

115. Novartis routinely paid physicians kickbacks in the form of so-called "speaking fees" as a reward for prescribing high volumes of Novartis drugs and in order to influence other physicians to prescribe Novartis drugs.

116. For example, Mr. Van Glahn had a $30,000-per-month budget to carry out Novartis's routine practice of paying physicians up to $5,000 each to give a five-minute speech on Miacalcin Nasal Spray to some of the 300 physicians with whom Mr. Van Glahn had a sales relationship. For this purpose, Mr. Van Glahn organized meetings held at local restaurants and similar venues.

117. Mr. Van Glahn selected as speakers those physicians who prescribed high volumes of Miacalcin Nasal Spray or other Novartis drugs. This was done as both a reward to high-prescribing physicians, and since Novartis considered such physicians to have the most potential to influence the prescribing habits of other physicians.

118. Mr. Van Glahn's District Manager reviewed the volume of Novartis prescriptions generated by each physician Mr. Van Glahn proposed as a speaker and, if the volume was acceptably high, authorized the payments.

3. **All of the Alleged Misconduct Constituted Kickbacks and Illegal Referrals.**

119. Novartis's payment of money or providing things of value to the physician,

separately and together were, in each instance, the provision of something of value to the physician, either directly or indirectly, as an inducement or reward for prescribing Novartis drugs. Such conduct constituted kickbacks in violation of the Anti-Kickback Act and/or the Anti-Kickback Statute, and the participation in illegal referrals in violation of the Stark Law, as well as violations of similarly applicable state laws. At its core, such misconduct subverted and undermined the physician's independent medical judgment.

D. <u>Conclusion</u>.

120. Novartis knowingly engaged in the fraudulent conduct described in this Complaint in order to increase its market share and enrich itself. Moreover, Novartis further enriched itself by providing false information to the government in order to conceal and otherwise avoid its obligations under the Medicaid Rebate Statute to pay larger Medicaid rebates.

121. By paying kickbacks to physicians, Novartis violated applicable statutes and regulations, including, but not limited to, the Anti-Kickback Act, the Anti-Kickback Statute, the Stark Law, and the False Claims Act. In violating the law, Novartis encouraged overutilization of potentially unnecessary prescription drugs by doctors, induced excessive payments from government-funded health insurance programs, and undermined physicians' and patients' freedom to exercise judgment and choose appropriate drug therapies, which created the potential for patient harm, but generated additional income.

122. The Government has deemed such misconduct to be material to its decision to pay healthcare claims, in part through its requirement that providers certify compliance with those laws as a condition of payment under, and participation in, Government healthcare programs. If the Government had been aware that drugs were prescribed as a result of such prohibited conduct, the Government would not have paid the claims submitted as a result of Novartis'

wrongdoing.

123. Had government-funded health insurance programs been aware that drugs were prescribed as a result of the conduct alleged in this Amended Complaint, they would not have paid the unqualified claims submitted as a result of Defendants' wrongdoing.

124. In addition, knowing of the dire consequences of discovery of its unlawful kickback scheme should it be uncovered, Novartis submitted false "Best Price" data to the government to avoid paying higher Medicaid rebates and to conceal its illegal activities from the government.

125. Furthermore, Novartis did not report these payments or benefits to Medicare, Medicaid or other government-funded programs. Thus, Novartis facilitated and caused each recipient health care provider to falsely certify, either expressly or impliedly, that it had complied with the aforesaid laws and was qualified to participate in Medicare, Medicaid and other government-funded programs and, in particular, qualified to receive reimbursements thereunder, in violation of law.

126. As a result, Government-funded health insurance programs paid hundreds of millions of dollars in reimbursements for Novartis prescription drugs that were prescribed by physicians, in part, because of the payment of unlawful kickbacks by Novartis, and failed to realize the full value of statutorily required rebates due to Novartis' underreporting of its "Best Price."

VII. CLAIMS FOR RELIEF.

FIRST CAUSE OF ACTION

(False Claims Act: Presentation of False Claims)
(31 U.S.C. § 3729(a)(1))

127. Relator repeats and incorporates by reference the allegations contained in Paragraphs 1 through 126 of this Amended Complaint as if fully set forth herein.

128. As more particularly set forth in the foregoing paragraphs, by virtue of the acts alleged herein the Defendants knowingly presented or caused to be presented to officers or employees of the United States Government false or fraudulent claims for payment or approval in violation of 31 U.S.C. § 3729(a)(1).

SECOND CAUSE OF ACTION

(False Claims Act: Making or Using False Record or Statement to Cause Claim to be Paid)
(31 U.S.C. § 3729(a)(2))

129. Relator repeats and incorporates by reference the allegations contained in Paragraphs 1 through 128 of this Amended Complaint as if fully set forth herein.

130. As more particularly set forth in the foregoing paragraphs, by virtue of the acts alleged herein the Defendants knowingly made, used, or caused to be made or used false records or statements to get false or fraudulent claims paid or approved by the government in violation of 31 U.S.C. § 3729(a)(2).

THIRD CAUSE OF ACTION

(False Claims Act: Making or Using False Record Or Statement to Avoid an Obligation to Refund)
(31 U.S.C. § 3729(a)(7))

131. Relator repeats and incorporates by reference the allegations contained in Paragraphs 1 through 130 of this Amended Complaint as if fully set forth herein.

132. As more particularly set forth in the foregoing paragraphs, by virtue of the acts alleged herein the Defendants knowingly made, used or caused to be made or used false records or false statements when reporting "Best Price" information and paying rebates concerning Visudyne, in violation of 42 U.S.C. § 1396r-8, all in an effort to avoid or decrease an obligation to pay or transmit money or property to the United States.

FOURTH CAUSE OF ACTION

(False or Fraudulent Claims That Were the Product of Violations of the Anti-Kickback Act)

133. Plaintiff repeats and incorporates by reference the allegations contained in Paragraphs 1 through 132 of this Amended Complaint as if fully set forth herein.

134. By engaging in the conduct described in the foregoing paragraphs, Defendants violated 41 U.S.C. §§ 52-53.

135. Defendants knowingly caused physicians, other healthcare providers and/or beneficiaries to present claims to the United States Government and to Medicaid that were the product of the payment of the above-described kickbacks. The payment of a kickback to induce a prescription constitutes a "thing of value . . . for the purpose of improperly obtaining or rewarding favorable treatment," which was designed to and in fact did increase the level of business in violation of the Anti-Kickback Act. 41 U.S.C. § 52.

136. Novartis did not report these payments to Medicare, Medicaid or other government-funded programs. Thus, Novartis facilitated and caused each recipient health care provider to falsely certify, either expressly or impliedly, that it had complied with the aforesaid laws and was qualified to participate in Medicare, Medicaid and other government-funded programs and, in particular, qualified to receive reimbursements thereunder.

137. As a result of the conduct set forth in this cause of action, the Government

suffered harm as a result of paying and reimbursing for pharmaceuticals which, had the Government known such pharmaceuticals were prescribed as a result of kickbacks, the Government would not otherwise have paid for and/or reimbursed.

FIFTH CAUSE OF ACTION

(False or Fraudulent Claims That were the Product of Violations of the Anti-Kickback Statute)

138. Relator repeats and incorporates by reference the allegations contained in Paragraphs 1 through 137 of this Amended Complaint as if fully set forth herein.

139. By engaging in the conduct described in the foregoing paragraphs, Defendants have violated 42 U.S.C. §§ 1320a-7a.

140. Defendants knowingly caused physicians and other healthcare providers and beneficiaries to present claims to the United States Government and to Medicaid that were the product of the payment of the above-described kickbacks, which constitute remuneration to increase the level of business in violation of 42 U.S.C. § 1320a-7a(a)(7) which incorporates by reference 42 U.S.C. § 1320a-7b(b)(1)&(2), and for which Defendants are liable for a civil penalty of $50,000 for each act that violated 42 U.S.C. § 1320a-7a(a)(7), pursuant to 42 U.S.C. § 1320a-7a(a).

141. Novartis did not report these payments to Medicare, Medicaid or other government-funded programs. Thus, Novartis facilitated and caused each recipient health care provider to falsely certify, either expressly or impliedly, that it had complied with the aforesaid laws and was qualified to participate in Medicare, Medicaid and other government-funded programs and, in particular, qualified to receive reimbursements thereunder.

142. As a result of the conduct set forth in this cause of action, the Government suffered harm as a result of paying and reimbursing for pharmaceuticals which, had the

Government known such pharmaceuticals were prescribed as a result of kickbacks or other prohibited forms of remuneration, the Government would not otherwise have paid for and/or reimbursed.

SIXTH CAUSE OF ACTION

(False or Fraudulent Claims That Were the Product of Violations of the Stark Law)

143. Plaintiff repeats and incorporates by reference the allegations contained in Paragraphs 1 through 142 of this Amended Complaint as if fully set forth herein.

144. By engaging in the conduct described in the foregoing paragraphs, Defendants have violated the Stark Law, codified at 42 U.S.C. § 1395nn and further implemented at 42 C.F.R. §§ 411.350 *et seq.*

145. Defendants have knowingly caused physicians to "make a referral to the entity for the furnishing of designated health services for which payment otherwise may be made under this subchapter," in violation of 42 U.S.C. § 1395nn(a) and 42 C.F.R. § 411.353, and for which Defendants are liable for a civil penalty of $15,000 for each such claim, pursuant to 42 U.S.C. § 1395nn(g)(3).

146. Defendants have knowingly entered into improper arrangements or schemes with physicians in violation of 42 U.S.C. § 1395nn(a) and 42 C.F.R. § 411.353, and for which Defendants are liable for a civil penalty of $100,000 "for each such arrangement or scheme," pursuant to 42 U.S.C. § 1395nn(g)(4).

147. Novartis did not report these payments to Medicare, Medicaid or other government-funded programs. Thus, Novartis facilitated and caused each recipient health care provider to falsely certify, either expressly or impliedly, that it had complied with the aforesaid laws and was qualified to participate in Medicare, Medicaid and other government-funded

programs and, in particular, qualified to receive reimbursements thereunder.

148. As a result of the conduct set forth in this cause of action, the Government suffered harm as a result of paying and reimbursing for pharmaceuticals which, had the Government known such pharmaceuticals were prescribed as a result of kickbacks or other prohibited forms of remuneration, the Government would not otherwise have paid for and/or reimbursed.

SEVENTH CAUSE OF ACTION

(California False Claims Act)
(Cal. Govt. Code §§ 12650 *et seq.*)

149. Plaintiff repeats and incorporates by reference the allegations contained in Paragraphs 1 through 148 of this Amended Complaint as if fully set forth herein.

150. By virtue of the acts described above, Defendants "[k]nowingly present[ed] or cause[d] to be presented to an officer or employee of the state or of any political subdivision thereof, a false claim for payment or approval," in violation of Cal. Gov't Code § 12651(a)(1).

151. By virtue of the acts described above, Defendants "[k]nowingly ma[de], use[d], or cause[d] to be made or used a false record or statement to get a false claim paid or approved by the state or by any political subdivision," in violation of Cal. Gov't Code § 12651(a)(2).

152. By virtue of the acts described above, Defendants "[k]nowingly ma[de], use[d], or cause[d] to be made or used a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the state or to any political subdivision," specifically when reporting "best price" information and paying rebates concerning Visudyne, in violation of 42 U.S.C. § 1396r-8, all in violation of Cal. Gov't Code § 12651(a)(7).

153. The California State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by

Defendants, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

154. By reason of the Defendants' acts, the State of California has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

155. Pursuant to Cal. Gov't Code § 12651(a), the State of California is entitled to three times the amount of actual damages plus the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

EIGHTH CAUSE OF ACTION

(Delaware False Claims And Reporting Act)
(Del Code Ann. tit. 6, §§ 1201 *et seq.*)

156. Plaintiff repeats and incorporates by reference the allegations contained in Paragraphs 1 through 148 of this Amended Complaint as if fully set forth herein.

157. By virtue of the acts described above, Defendants "[k]nowingly present[ed], or cause[d] to be presented, directly or indirectly, to an officer or employee of the Government a false or fraudulent claim for payment or approval," in violation of Del Code Ann. tit. 6, § 1201(a)(1).

158. By virtue of the acts described above, Defendants "[k]nowingly ma[de], use[d], or cause[d] to be made or used, directly or indirectly, a false record or statement to get a false or fraudulent claim paid or approved," in violation of Del Code Ann. tit. 6, § 1201(a)(2).

159. By virtue of the acts described above, Defendants "[k]nowingly ma[de], use[d or cause[d] to be made or used a false record or statement to conceal, avoid, increase or decrease an obligation to pay or transmit money or property to or from the Government," specifically when reporting "best price" information and paying rebates concerning Visudyne, in violation of 42

U.S.C. § 1396r-8, all in violation of Del Code Ann. tit. 6, § 1201(a)(7).

160. The Delaware State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

161. By reason of the Defendants' acts, the State of Delaware has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

162. Pursuant to Del Code Ann. tit. 6, § 1201(a), the State of Delaware is entitled to three times the amount of actual damages plus the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

NINTH CAUSE OF ACTION

(Florida False Claims Act)
(Fla. Stat. §§ 68.081 *et seq.*)

163. Plaintiff repeats and incorporates by reference the allegations contained in Paragraphs 1 through 148 of this Amended Complaint as if fully set forth herein.

164. By virtue of the acts described above, Defendants "[k]nowingly present[ed] or cause[d] to be presented to an officer or employee of an agency a false or fraudulent claim for payment or approval," in violation of Fla. Stat. § 68.082(2)(a).

165. By virtue of the acts described above, Defendants "[k]nowingly ma[de], use[d], or cause[d] to be made or used a false record or statement to get a false or fraudulent claim paid or approved by an agency," in violation of Fla. Stat. § 68.082(2)(b).

166. By virtue of the acts described above, Defendants "[k]nowingly ma[de], use[d], or cause[d] to be made or used a false record or statement to conceal, avoid, or decrease an

obligation to pay or transmit money or property to an agency," specifically when reporting "best price" information and paying rebates concerning Visudyne, in violation of 42 U.S.C. § 1396r-8, all in violation of Fla. Stat. § 68.082(2)(g).

167. The Florida State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

168. By reason of the Defendants' acts, the State of Florida has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

169. Pursuant to Fla. Stat. § 68.082(2), the State of Florida is entitled to three times the amount of actual damages plus the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

TENTH CAUSE OF ACTION

(Hawaii False Claims Act)
(Haw. Rev. Stat. §§ 661-21 *et seq.*)

170. Plaintiff repeats and incorporates by reference the allegations contained in Paragraphs 1 through 148 of this Amended Complaint as if fully set forth herein.

171. By virtue of the acts described above, Defendants "[k]nowingly present[ed], or cause[d] to be presented, to an officer or employee of the State a false or fraudulent claim for payment or approval," in violation of Haw. Rev. Stat. § 661-21(a)(1).

172. By virtue of the acts described above, Defendants "[k]nowingly ma[de], use[d], or cause[d] to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State," in violation of Haw. Rev. Stat. § 661-21(a)(2).

173. By virtue of the acts described above, Defendants "[k]nowingly ma[de], use[d], or cause[d] to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State," specifically when reporting "best price" information and paying rebates concerning Visudyne, in violation of 42 U.S.C. § 1396r-8, all in violation of Haw. Rev. Stat. § 661-21(a)(7).

174. The Hawaii State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

175. By reason of the Defendants' acts, the State of Hawaii has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

176. Pursuant to Haw. Rev. Stat. § 661-21(a), the State of Hawaii is entitled to three times the amount of actual damages plus the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

ELEVENTH CAUSE OF ACTION

(Illinois Whistleblower Reward And Protection Act)
(740 Ill. Comp. Stat. §§ 175/1 *et seq.*)

177. Plaintiff repeats and incorporates by reference the allegations contained in Paragraphs 1 through 148 of this Amended Complaint as if fully set forth herein.

178. By virtue of the acts described above, Defendants "knowingly present[ed], or cause[d] to be presented, to an officer or employee of the State or a member of the Guard a false or fraudulent claim for payment or approval," in violation of 740 Ill. Comp. Stat. § 175/3(a)(1).

179. By virtue of the acts described above, Defendants "knowingly ma[de], use[d], or

cause[d] to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State," in violation of 740 Ill. Comp. Stat. § 175/3(a)(2).

180. By virtue of the acts described above, Defendants "knowingly ma[de], use[d], or cause[d] to be made or used, a false record or statement to conceal, avoid or decrease an obligation to pay or transmit money or property to the State," specifically when reporting "best price" information and paying rebates concerning Visudyne, in violation of 42 U.S.C. § 1396r-8, all in violation of 740 Ill. Comp. Stat. § 175/3(a)(7).

181. The Illinois State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

182. By reason of the Defendants' acts, the State of Illinois has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

183. Pursuant to 740 Ill. Comp. Stat. § 175/3(a), the State of Illinois is entitled to three times the amount of actual damages plus the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

TWELFTH CAUSE OF ACTION

(Louisiana False Claims Act/Medical Assistance Programs Integrity Law)
(46 La. Rev. Stat. ch. 3 §§ 437.1 *et seq.*)

184. Plaintiff repeats and incorporates by reference the allegations contained in Paragraphs 1 through 148 of this Amended Complaint as if fully set forth herein.

185. By virtue of the acts described above, Defendants "offer[ed], or pa[id] . . . remuneration, including but not limited to kickbacks . . . , directly or indirectly, overtly or

covertly, in cash or in kind, for . . . [a] good, supply, or service for which payment may be made, in whole or in part, under the medical assistance programs," in violation of 46 La. Rev. Stat. ch. 3 § 438.2(A)(1).

186. By virtue of the acts described above, Defendants "knowingly present[ed] or cause[d] to be presented a false or fraudulent claim," in violation of 46 La. Rev. Stat. ch. 3 § 438.3(A).

187. By virtue of the acts described above, Defendants "knowingly engage[d] in misrepresentation to obtain, or attempt to obtain, payment from medical assistance programs funds," in violation of 46 La. Rev. Stat. ch. 3 § 438.3(B).

188. The Louisiana State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

189. By reason of the Defendants' acts, the State of Louisiana has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

190. Pursuant to 46 La. Rev. Stat. ch. 3 § 438.6, the State of Louisiana is entitled to three times the amount of actual damages plus the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

THIRTEENTH CAUSE OF ACTION

(Massachusetts False Claims Law)
(Mass. Gen. Laws ch. 12, §§ 5A *et seq.*)

191. Plaintiff repeats and incorporates by reference the allegations contained in Paragraphs 1 through 148 of this Amended Complaint as if fully set forth herein.

192. By virtue of the acts described above, Defendants "knowingly present[ed], or cause[d] to be presented, a false or fraudulent claim for payment or approval," in violation of Mass. Gen. Laws ch. 12, § 5B(1).

193. By virtue of the acts described above, Defendants "knowingly ma[de], use[d], or cause[d] to be made or used, a false record or statement to obtain payment or approval of a claim by the commonwealth or any political subdivision thereof," in violation of Mass. Gen. Laws ch. 12, § 5B(2).

194. By virtue of the acts described above, Defendants "knowingly ma[de], use[d], or cause[d] to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or to transmit money or property to the commonwealth or political subdivision thereof," specifically when reporting "best price" information and paying rebates concerning Visudyne, in violation of 42 U.S.C. § 1396r-8, all in violation of Mass. Gen. Laws ch. 12, § 5B(8).

195. The Massachusetts Commonwealth Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

196. By reason of the Defendants' acts, the Commonwealth of Massachusetts has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

197. Pursuant to Mass. Gen. Laws ch. 12, § 5B, the Commonwealth of Massachusetts is entitled to three times the amount of actual damages plus the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

FOURTEENTH CAUSE OF ACTION

(Nevada False Claims Act)
(Nev. Rev. Stat. §§ 357.010 *et seq.*)

198. Plaintiff repeats and incorporates by reference the allegations contained in Paragraphs 1 through 148 of this Amended Complaint as if fully set forth herein.

199. By virtue of the acts described above, Defendants "[k]nowingly present[ed] or cause[d] to be presented a false claim for payment or approval," in violation of Nev. Rev. Stat. § 357.040(1)(a).

200. By virtue of the acts described above, Defendants "[k]nowingly ma[de] or use[d], or cause[d] to be made or used, a false record or statement to obtain payment or approval of a false claim," in violation of Nev. Rev. Stat. § 357.040(1)(b).

201. By virtue of the acts described above, Defendants "[k]nowingly ma[de] or use[d], or cause[d] to be made or used, a false record or statement to conceal, avoid or decrease an obligation to pay or transmit money or property to the state or a political subdivision," specifically when reporting "best price" information and paying rebates concerning Visudyne, in violation of 42 U.S.C. § 1396r-8, all in violation of Nev. Rev. Stat. § 357.040(1)(g).

202. The Nevada State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

203. By reason of the Defendants' acts, the State of Nevada has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

204. Pursuant to Nev. Rev. Stat. § 357.040(1), the State of Nevada is entitled to three times the amount of actual damages plus the maximum penalty of $10,000 for each and every

false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

FIFTEENTH CAUSE OF ACTION

(New Mexico False Claims Act)
(N.M. Stat. §§ 27-14-1 *et seq.*)

205. Plaintiff repeats and incorporates by reference the allegations contained in Paragraphs 1 through 148 of this Amended Complaint as if fully set forth herein.

206. By virtue of the acts described above, the Defendants "present[ed], or cause[d] to be presented, to the state a claim for payment under the Medicaid program knowing that such claim is false or fraudulent," in violation of N.M. Stat. § 27-14-4(A).

207. By virtue of the acts described above, the Defendants "ma[de], use[d] or cause[d] to be made or used a record or statement to obtain a false or fraudulent claim under the Medicaid program paid for or approved by the state knowing such record or statement is false," in violation of N.M. Stat. § 27-14-4(C).

208. By virtue of the acts described above, the Defendants "ma[de], use[d] or cause[d] to be made or used a record or statement to conceal, avoid or decrease an obligation to pay or transmit money or property to the state, relative to the Medicaid program, knowing that such record or statement is false," specifically when reporting "best price" information and paying rebates concerning Visudyne, in violation of 42 U.S.C. § 1396r-8, all in violation of N.M. Stat. § 27-14-4(E).

209. The New Mexico State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by the Defendants, paid and continues to pay the claims that would not be paid, but for the acts and/or conduct of Defendants as alleged herein.

210. By reason of the Defendants' acts, the State of New Mexico has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

211. Pursuant to N.M. Stat. § 27-14-4, the State of New Mexico is entitled to three times the amount of actual damages plus the maximum penalty which may be applicable for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by the Defendants.

SIXTEENTH CAUSE OF ACTION

(New York False Claims Act N.Y. Fin. Law §§ 187 *et seq.*)

212. Plaintiff repeats and incorporates by reference the allegations contained in Paragraphs 1 through 148 of this Second Amended Complaint.

213. By virtue of the acts described above, Defendants "knowingly present[ed], or cause[d] to be presented, to any employee, officer or agent of the state or a local government, a false or fraudulent claim for payment or approval," in violation of N.Y. Fin. Law § 189.1(a).

214. By virtue of the acts described above, Defendants "knowingly ma[de], use[d], or cause[d] to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the state or a local government," in violation of N.Y. Fin. Law § 189.1(b).

215. By virtue of the acts described above, Defendants "knowingly ma[de], use[d], or cause[d] to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the state or a local government," specifically when reporting "best price" information and paying rebates concerning Visudyne, in violation of 42 U.S.C. § 1396r-8, all in violation of N.Y. Fin. Law § 189.1(g).

216. The New York State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by the

Defendants, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

217. By reason of the Defendants' acts, the State of New York has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

218. Pursuant to N.Y. Fin. Law § 189.1, the State of New York is entitled to three times the amount of actual damages plus the maximum penalty of $12,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

SEVENTEENTH CAUSE OF ACTION

(Tennessee Medicaid False Claims Act)
(Tenn. Code §§ 71-5-181 *et seq.*)

219. Plaintiff repeats and incorporates by reference the allegations contained in Paragraphs 1 through 148 of this Amended Complaint as if fully set forth herein.

220. By virtue of the acts described above, Defendants "[p]resent[ed], or cause[d] to be presented, to the state a claim for payment under the Medicaid program knowing such claim is false or fraudulent," in violation of Tenn. Code § 71-5-182(a)(1)(A).

221. By virtue of the acts described above, Defendants "[m]a[de], use[d], or cause[d] to be made or used, a record or statement to get a false or fraudulent claim under the Medicaid program paid for or approved by the state knowing such record or statement is false," in violation of Tenn. Code § 71-5-182(a)(1)(B).

222. By virtue of the acts described above, Defendants "[m]a[de], use[d], or cause[d] to be made or used, a record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the state, relative to the Medicaid program, knowing such record or statement is false," specifically when reporting "Best Price" information and paying rebates

concerning Visudyne, in violation of 42 U.S.C. § 1396r-8, all in violation of Tenn. Code § 71-5-182(a)(1)(D).

223. The Tennessee State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

224. By reason of the Defendants' acts, the State of Tennessee has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

225. Pursuant to Tenn. Code § 71-5-182(a)(1), the State of Tennessee is entitled to three times the amount of actual damages plus the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

EIGHTEENTH CAUSE OF ACTION

(Texas Medicaid Fraud Prevention Law)
(Tex. Hum. Res. Code §§ 36.001 *et seq.*)

226. Plaintiff repeats and incorporates by reference the allegations contained in Paragraphs 1 through 148 of this Amended Complaint as if fully set forth herein.

227. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Texas State Government for payment or approval, in violation of Tex. Hum. Res. Code § 36.002(6).

228. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Texas State Government to approve and pay such false and fraudulent claims, in violation of Tex. Hum. Res. Code § 36.002.

229. By virtue of the acts described above, Defendants "knowingly ma[de], use[d], or cause[d] the making or use of a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to this state under the Medicaid program," specifically when reporting "best price" information and paying rebates concerning Visudyne, in violation of 42 U.S.C. § 1396r-8, all in violation of Tex. Hum. Res. Code § 36.002(12).

230. The Texas State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

231. By reason of the Defendants' acts, the State of Texas has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

232. Pursuant to Tex. Hum. Res. Code § 36.052, the State of Texas is entitled to two times the amount of actual damages plus the maximum penalty of $15,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

NINETEENTH CAUSE OF ACTION

(Virginia Fraud Against Taxpayers Act)
(Va. Code §§ 8.01-216.1 *et seq.*)

233. Plaintiff repeats and incorporates by reference the allegations contained in Paragraphs 1 through 148 of this Amended Complaint as if fully set forth herein.

234. By virtue of the acts described above, Defendants "[k]nowingly present[ed], or cause[d] to be presented, to an officer or employee of the Commonwealth a false or fraudulent claim for payment or approval," in violation of Va. Code § 8.01-216.3(A)(1).

235. By virtue of the acts described above, Defendants "[k]nowingly ma[de], use[d], or

cause[d] to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Commonwealth," in violation of Va. Code § 8.01-216.3(A)(2).

236. By virtue of the acts described above, Defendants "[k]nowingly ma[de], use[d], or cause[d] to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Commonwealth," specifically when reporting "best price" information and paying rebates concerning Visudyne, in violation of 42 U.S.C. § 1396r-8, all in violation of Va. Code § 8.01-216.3(A)(7).

237. The Virginia Commonwealth Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

238. By reason of the Defendants' acts, the Commonwealth of Virginia has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

239. Pursuant to Va. Code § 8.01-216.3(A), the Commonwealth of Virginia is entitled to three times the amount of actual damages plus the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

TWENTIETH CAUSE OF ACTION

(District of Columbia False Claims Act)
(D.C. Code §§ 2-308.03 *et seq.*)

240. Plaintiff repeats and incorporates by reference the allegations contained in Paragraphs 1 through 148 of this Amended Complaint as if fully set forth herein.

241. By virtue of the acts described above, Defendants "[k]nowingly present[ed], or cause[d] to be presented, to an officer or employee of the District a false claim for payment or

approval," in violation of D.C. Code § 2-308.14(a)(1).

242. By virtue of the acts described above, Defendants "[k]nowingly ma[de], use[d], or cause[d] to be made or used, a false record or statement to get a false claim paid or approved by the District," in violation of D.C. Code § 2-308.14(a)(2).

243. By virtue of the acts described above, Defendants "[k]nowingly ma[de] or use[d], or cause[d] to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the District," specifically when reporting "Best Price" information and paying rebates concerning Visudyne, in violation of 42 U.S.C. § 1396r-8, all in violation of D.C. Code § 2-308.14(a)(7).

244. The District of Columbia Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

245. By reason of the Defendants' acts, the District of Columbia has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

246. Pursuant to D.C. Code § 2-308.14(a), the District of Columbia is entitled to three times the amount of actual damages plus the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

VIII. DEMANDS FOR RELIEF.

WHEREFORE, Relator, on behalf of the United States Government, demands judgment against the above-named Defendants, ordering:

As to the Federal Claims:

a. Pursuant to 31 U.S.C. § 3729(a), Defendants pay an amount equal to three times the amount of damages the United States Government has sustained as a result of Defendants' actions, plus a civil penalty of not less than $6,500 and not more than $11,000 for each violation of 31 U.S.C. §§ 3729(a) or such other penalty as the law may permit and/or require for each violation of other laws which governed Defendants' conduct, *i.e.*, $50,000 for each violation of 42 U.S.C. § 1320a-7a(7) of the Anti-Kickback Statute;

b. Relator be awarded his relator's share of the judgment to the maximum amount provided pursuant to 31 U.S.C. § 3730(d) of the False Claims Act and/or any other applicable provision of law;

c. Relator be awarded all costs and expenses of this action, including attorneys' fees as provided by 31 U.S.C. § 3730(d) and any other applicable provision of the law; and

d. Relator and the United States of America be awarded such other and further relief as the Court may deem to be just and proper.

As to the State Claims:

f. Relator and each named State Plaintiff be awarded statutory damages in an amount equal to three times the amount of actual damages sustained by each State as a result of Defendants' actions, as well as the maximum statutory civil penalty for each violation by Defendants within each State, all as provided by:

Cal. Govt. Code § 12651;
Del Code Ann. tit. 6, § 1201;
Fla. Stat. § 68.082;
Haw. Rev. Stat. § 661-21;
740 Ill. Comp. Stat. § 175/3;
La. Rev. Stat. § 46:439.6 ;
Mass. Gen. Laws ch. 12, § 5B.;
Nev. Rev. Stat. § 357.040;

N.M. Stat. § 27-14-4;
N.Y. Fin. Law § 189.1(g)
Tenn. Code § 71-5-182;
Va. Code § 8.01-216.3; and
D.C. Code § 2-308.14;

g. Relator and Plaintiff State of Texas be awarded statutory damages in an amount equal to two times the amount of actual damages that Texas has sustained as a result of the Defendants' actions within Texas, as well as the maximum statutory civil penalty for each violation of Tex. Hum. Res. Code § 36.052;

h. Relator be awarded his relator's share of any judgment to the maximum amount provided pursuant to

Cal. Govt. Code § 12652(g);
Del Code Ann. tit. 6, § 1205;
Fla. Stat. § 68.085;
Haw. Rev. Stat. § 661-27;
740 Ill. Comp. Stat. § 175/4(d);
La. Rev. Stat. § 46:439.4;
Mass. Gen. Laws ch. 12, § 5F.;
Nev. Rev. Stat. § 357.210;
N.M. Stat. § 27-14-9;
N.Y. Fin. Law § 190.6
Tenn. Code § 71-5-183(c);
Tex. Hum. Res. Code § 36.110;
Va. Code § 8.01-216.7; and
D.C. Code § 2-308.15;

i. Relator be awarded all costs and expenses associated with each of the pendent State claims, plus attorney's fees as provided pursuant to:

Cal. Govt. Code § 12652(g)(8);
Del Code Ann. tit. 6, § 1205;
Fla. Stat. § 68.086;
Haw. Rev. Stat. § 661-27;
740 Ill. Comp. Stat. § 175/4(d);
La. Rev. Stat. § 46:439.6;
Mass. Gen. Laws ch. 12, § 5F.;
Nev. Rev. Stat. § 357.180;
N.M. Stat. § 27-14-9;

N.Y. Fin. Law § 190.7
Tenn. Code § 71-5-183(c);
Tex. Hum. Res. Code § 36.110;
Va. Code § 8.01-216.7; and
D.C. Code § 2-308.15; and

j. Relator and the State Plaintiffs be awarded such other and further relief as the Court may deem to be just and proper.

TRIAL BY JURY

Relator hereby demands a trial by jury as to all issues.

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Dated: September 18, 2008